OncoHealth

Blincyto (Blinatumomab)

Effective Date: 9/1/20
Revision Date(s): 9/21, 8/22, 9/23
Review Date: 9/19/2023
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria:

Acute Lymphoblastic Leukemia – Relapsed/Refractory

- Patient is at least 15 years old;
    - Patient has Philadelphia chromosome positive disease
        - As a single agent or in combination with a TKI; OR
        - In combination with inotuzumab ozogamicin + mini-hyperCVD[1]
    - Patient has Philadelphia chromosome negative disease
        - As a single agent

Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
    - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Thompson Micromedex DrugDex® (Class I and IIa)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals

- American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
- **Meeting abstracts and case reports are excluded from consideration.**

- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Blincyto	J9039	Inj., blinatumomab, 1 mcg

References

1. Blincyto. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/ Accessed 9/1/2023
2. Blincyto [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/blincyto/blincyto_pi_hcp_english.pdf Accessed 9/1/2023
3. Acute Lymphoblastic Leukemia: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed 9/1/23
4. Pediatric Acute Lymphoblastic Leukemia: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed 9/1/23

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state

regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

For Internal Use ONLY

Date	Updates
10/2022	Updated to new format Updated to reflect current NCCN Guidelines
9/2023	Removed indications without inconsistencies between FDA and NCCN; updated formatting for clarity. No clinical changes to UM criteria. Added standard language regarding FDA/NCCN indications under universal criteria